

K243705 Saige-Density (2.5.0)Dec 19, 2024
20 days to decisionK243705 · Product code: **QIH** · Radiology
Source: <https://www.510kdatabase.net/k243705/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Automated Radiological Image Processing Software (QIH)
Date received	Nov 29, 2024
Decision date	Dec 19, 2024
Days to decision	20 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	DeepHealth, Inc.
Location	Cambridge, MA, US
Contact	B. Nathan Hunt
510(k) history	8 submissions · 8 cleared · 2021-2025

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